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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,730	01/17/2002	Brooks Edwards	9550-001-27	2580

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Supervisor, Patent Prosecution Services
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Washington, DC 20036-2412

EXAMINER

CEPERLEY, MARY

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/046,730

Applicant(s)

EDWARDS ET AL.

Examiner

Mary (Molly) E. Ceperley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-67 is/are pending in the application.
- 4a) Of the above claim(s) 32-52 and 59-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 and 53-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>04/16/2002</u> . | 6) <input type="checkbox"/> Other: _____ |

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1) Applicant's election with traverse of Group I, claims 1-31 and 53-58, in the response filed January 29, 2004 is acknowledged. The traversal is on the ground(s) that there would be no undue burdensome search involved in searching all of the inventions. This is not found persuasive because the searches for the multiple inventions are not coextensive as set forth in paragraph **1)** of the restriction requirement. Applicant's statement that "all the claims in the instant application are related to a solid support comprising a functional polymer layer optimized for chemiluminescent detection" this is not, in fact, the case. For example, claim 32 (Group III), drawn to a solid support comprised of a polymer layer and a cationic microgel, does not require the presence of any chemiluminescence-enhancing "quaternary onium polymer". Further, for example, neither the multi-component kit of claim 52 (Group IV) nor the solid support of claim 66 (Group V) requires the presence of any chemiluminescence-enhancing "quaternary onium polymer". A statement of the different patentability considerations involved in examining the distinct groups is set forth in the last subparagraph of paragraph **2)** of the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-31 and 53-58 are treated on the merits in this Office action. Claims 32-52 and 59-67 are withdrawn from further consideration as being drawn to non-elected inventions.

2) Although specific claims are cited in the rejections below, these rejections are also applicable to all other claims in which the noted problems/language occur.

3) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4) The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5) Claims 1, 4-9, 12-22 and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of "quaternary onium polymers" defined by the formula of claim 2, does not reasonably provide enablement for the preparation and use of all possible types of "quantum yield enhancing materials" (claim 1). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The term "quantum yield enhancing materials" is inclusive of moieties such as fluorescent ruthenium or terbium metal complexes as well as fluorescent acridinium esters which are neither described nor contemplated as part of the invention as it is described in the specification.

6) Claims 25-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no enabling written description in the specification of "quantum yield enhancing compounds" (claim 25) and also no written description in the specification of the term "a quaternary onium compound" of the formula shown in claim 27. The specification does not provide a description which would enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The term "quantum yield enhancing compound" is inclusive of moieties such as fluorescent ruthenium or terbium metal complexes as well as fluorescent acridinium esters which are neither described nor contemplated as part of the invention as it is described in the specification.

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7) Claims 1-5, 7-13, 15 and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no written description in the specification of a solid support in which the "probes" are "ionically attached to a surface of the solid support (claim 1).

8) Claims 1-6 and 9-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no enabling written description of the claim 1 term "probes for a biopolymer target". The specification at page 6, lines 4-5 describes a "biopolymer probe" and page 11, lines 5-8 describe a "probe" but there is no description nor definition of the term "target". This problem also exists for the term

9) Claims 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 22 it is unclear what is meant by the term "a component of an analyte". Conventionally in the immunoassay art, the "analyte" is the component of interest which is present in a sample which undergoes analysis. The term "a component of an analyte" implies that the moiety to be analyzed is only part of the "analyte".

10) The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12) Claims 1-31 and 53-58 are rejected under 35 U.S.C. 102(b)/103 as being anticipated by or obvious over Bronstein et al (U.S. 5,849,495).

The instant invention involves the concept of adding a "quaternary onium polymer" to a solid phase to enhance the "quantum yield" of the chemiluminescent signal produced during the detection of an analyte captured on the solid phase (see instant claim 1).

Bronstein et al describe this same concept and provide a description of **a)** a solid support containing a quaternary ammonium polymer with probes attached as described in instant claim 1: see Bronstein et al, col. 13, line 32 – col. 14, line 14; col. 11, line 25 – col. 12, line 57; **b)** a kit comprising a solid support, a dioxetane substrate and antibody-enzyme complex as described in instant claim 22: see Bronstein et al, col. 7, lines 33-53; **c)** a method of modifying a solid support to include a quaternary ammonium polymer as described in instant claim 25: see Bronstein et al, col. 13, lines 31-54; **d)** a solid support as described in instant claim 53: see Bronstein et al, col. 13, lines 31-54. These descriptions in the reference anticipate the independent claims of the instant application.

The features of the dependent claims are either specifically described by the references (e.g. for the nucleic acid and protein probes of instant claims 7 and 8, see Bronstein et al, col. 7, lines 33-37) or constitute obvious variations in parameters which are routinely modified in the art (e.g. conventional

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methods for the preparation of quaternary onium polymer containing solid supports with attached probes, see Bronstein et al, col. 11, lines 11-20) and which have not been described as critical to the practice of the invention.

13) Claims 1-4, 8, 22-24 and 53-58 are rejected under 35 U.S.C. 102 (b) as being anticipated by over Bronstein et al (U.S. 5,336,596).

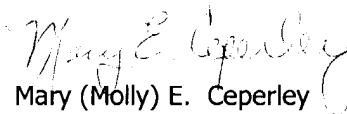
Bronstein et al describe a solid support useful in a chemiluminescence-based assay in which the solid support is coated with a quaternary onium polymer followed by coating of a probe. The reference describes and therefore anticipates the instantly claimed supports, kits and method of modifying a support to contain a quaternary onium polymer. See Bronstein et al, col. 3, lines 14-30; col. 3, line 62 – col. 4, line 68; col. 5, line 17 – col. 7, line 48; col. 8, lines 45-47; col. 10, "Detection of Proteins; Western Blotting"; Table of col. 13; claims 1-5.

14) An inquiry of a general nature which is **not related to the prosecution on the merits** should be directed to Technology Center 1600 telephone number (571) 272-1600. The general fax number for the USPTO is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823.

April 29, 2004


Mary (Molly) E. Ceperley
Primary Examiner
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